REMARKS

Claims 1 and 3-9 are currently pending in this application, claims 3-4 having been withdrawn from consideration pursuant to a restriction requirement made final. Claim 2 is cancelled by this amendment. Claim 9 is added by this amendment. Accordingly, claims 1 and 5-9 remain for consideration.

Claims 1-2 and 5-8 were rejected under the first paragraph of 35 U.S.C. § 112, allegedly for lack of enablement with respect to the range of activities recited in the claims.

Claims 1-2 and 5-8 were rejected under the second paragraph of 35 U.S.C. § 112 for indefiniteness.

Claim 2 was rejected under the second paragraph of 35 U.S.C. § 112 for being incomplete for omitting essential steps.

Claims 1-2 and 5-8 were rejected under 35 U.S.C. § 102(a) as anticipated by, or, in the alternative, under 35 U.S.C. § 103 as obvious over U.S. Patent No. 6,653,456 to Ghoshal et al. ("Ghoshal et al. '456").

Claims 1-2 and 5-8 were rejected under 35 U.S.C. § 102(a) as anticipated by, or, in the alternative, under 35 U.S.C. § 103 as obvious over U.S. Patent No. 5,618,795 to Kondo et al. ("Kondo et al. '795").

The three-month shortened statutory period for response expires on February 14, 2005 (February 12, 2005 is a Saturday and the period for response is therefore extended until February 14, 2005 pursuant to 37 C.F.R. § 1.7(a)). Accordingly, this response is being filed in a timely manner.

I. AMENDMENTS TO THE APPLICATION

Entry of the amendments to the application is respectfully requested. These amendments introduce no new matter.

Claim 1 is amended to clarify the claim and to remove language considered indefinite by the Examiner. Similar amendments are made to claim 5, 6, 7, and 8. Claim 6 is amended to clarify the organism or cell culture to which the compound is being administered. The method steps of new claim 9 are fully supported in the specification, e.g., at page 58, lines 3-16 and 59, lines 11-15.

Accordingly, entry of the amendments is respectfully requested.

Pursuant to the revised amendment practice under 37 C.F.R. §1.121, the amendments to the specification are made by presenting the amendments in marked up format to show changes made relative to the immediate prior version. The changes are shown by underlining the added matter, and double bracketing the deleted matter or presenting the deleted matter in strikethrough type. An accompanying clean version is not required and not presented, except for newly presented claim 9.

Entry of this amendment will merely: (1) correct word processing errors, which by its nature does not unduly interfere with the Examiner's preparation of subsequent office actions; and (2) modify certain language in the claims in order to conform to the requirements set forth in MPEP § 608.01(m), thus adding no new matter by way of such modifications. Furthermore, Applicant calls to the attention of the Examiner, as a courtesy, some very minor amendments, such as the addition of a comma in claims 5 and 6, after the word "mammals" and before the word "avian". Applicant is aware of the minuteness of such amendments and desires to inform the Examiner accordingly.

II. THE RESTRICTION REQUIREMENT

Applicant is in receipt of Examiner's repeated restriction requirement regarding Group I (claims 1-2 and 5-8, drawn to aminoglycosides, classified in class 536, subclass 17.2) and Group II (claims 3-4, drawn to cyclohexyl derivatives, classified in class 564, subclass 1+). Furthermore, Applicant acknowledges that such action is made final. However, Applicant respectfully retains the right to petition from the requirement and acknowledges such petition may be deferred until after final action on or allowance of claims to the invention elected under 37 C.F.R. 1.144. Applicant also respectfully retains the right to add claims to a reasonable number of species should a generic claim be found allowable pursuant to 37 C.F.R. § 1.141(a). Therefore, the remainder of Applicant's response shall be directed to the claims of the elected invention, namely claims 1-2 and 5-8 of the invention of Group I.

III. THE REJECTION UNDER 35 U.S.C. 112, FIRST PARAGRAPH

Examiner maintains a lack of enablement rejection regarding the claimed invention of Group I. Specifically, Examiner finds the specification does not "reasonably provide enablement for prophylaxis, amelioration or treatment of bacterial infections, viral infection, cancer or a genetic disorder...or for antiviral or antifungal activity...or for preventing the growth of bacteria." For the reasons set forth below, Applicant respectfully submits the application fully complies with the enablement requirement. Further, because the specification may expressly enable one skilled in the art to make and use the claimed invention, Applicant requests Examiner to withdraw the lack of enablement rejection.

The specification, at page 110 (Table 1) identifies representative agents from the aminoglycoside class of compounds having antimicrobial potency similar to that of tobramycin, which is a very potent aminoglycoside antibiotic. The Examples section of the specification (pages 81-109) teaches the synthesis of said aminoglycoside compounds. Furthermore, the synthesis identifies the relevant 2-deoxystreptamine (2-DOS) ring system important for the antimicrobial potency identified at Table 1. Because Table 1 demonstrates the 2-DOS pharmacophore as exhibiting antimicrobial effects, it is expected that the claimed structures containing the 2-DOS pharmacophore will have similar utility. Thus, since all the claimed structures contain the 2-DOS ring system, all are expected to have antimicrobial activity.

Applicant further submits the claimed compounds may be useful for the treatment or prophylaxis of bacterial infections as well as viral infections, cancers or genetic disorders based in part on the following reasoning. The claimed structures have multiple amino groups which will result in a net positive charge at physiologic pH conditions. In this state, the claimed structures will have the ability to form complexes with negatively charged RNA, thereby disrupting a variety of therapeutically relevant targets involved in viral replication. Examples include HIV-1 Rev-RRE, HIV-1 TAR, hepatitis delta virus, or cancer, including PAX3-FKHR or Bcr-Abl oncogenes. This is a well-understood mechanism of action. Moreover, since the 2-DOS ring system is known in the state of the art in the field to interfere with the ribosomal A-site, this site being responsible for translating messenger RNA into proteins, it is likely that these claimed compounds will affect gene expression. For these reasons, the claimed compounds will have a profound effect, not only on bacterial infections, but also in the therapeutic relief of viral infections, cancers or even genetic disorders.

Examiner further expresses doubt that a person of ordinary skill in the art would expect differing structures to have "the same utility." However, at the foundation of this doubt is the presumption that alterations to a compound's structure results in a dramatic change in said compound's utility. Granted, some changes will cause an effect,

such those changes vital enough to the compound's structure to elicit said functional change. Applicant has not disclosed or claimed such utility-altering modifications. The 2-DOS ring structure interferes with the ribosomal A-site, thereby disrupting messenger RNA translation into proteins. The claimed structures proffered by Applicant may differ slightly from each other based on varying side chains, but they all contain the 2-DOS ring structure. While the structural formulas may have some variation, the degree of variation does not rise to the level of altering the utility of the invention.

The presence of the 2-DOS pharmacophore, together with its well-understood mechanism of action in forming complexes with RNA, means that one of ordinary skill in the art understands these compounds to have appropriate activity in treating the conditions recited in the claims. A disclosed property of a chemical compound, such as the activity of the 2-DOS moiety of the claimed aminoglycosides, can fulfill the requirements for enablement of the first paragraph of 35 U.S.C. § 112 if persons skilled in the art to which that property pertains could use the compounds without undue experimentation and the compounds are derivatives related in their structure and their significant properties to a common and well-known family of useful compounds. *In re Folkers*, 145 U.S.P.Q. 390 (C.C.P.A. 1965). Even in areas considered unpredictable, such as organic chemistry or pharmacology, one need not necessarily disclose how to make and use each and every embodiment encompassed by the claim. *In re Angstadt*, 190 U.S.P.Q. 214 (C.C.P.A. 1976).

Examiner also states there is a lack of evidence showing the claimed compounds "are effective in prophylaxis of viral infections, cancer or a genetic disorder or have antifungal activity." Applicant respectfully disagrees with Examiner's "lack of evidence" rejection. Applicant's position is supported by the data from the specification (Table 1, pg. 110) showing evidence of the claimed compounds' antibacterial activity. Taking these data into account, as well as aminoglycoside antimicrobial potency and the 2-DOS ring structure, Applicant submits any further requirement for additional evidence would be tantamount to requesting human clinical trial data. The specification has

identified aminoglycosides as being potent antimicrobial antibiotics used in fighting a plethora of infectious agents. This information, combined with the evidence of the 2-DOS ring structure disrupting therapeutically relevant RNAs, is sufficient to expect the claimed compounds to be effective as vaccines, as well as prophylactic agents, against the named diseases.

Examiner also establishes a list (A-H) of additional matters to be addressed, to which the Applicant now responds.

(A) Examiner envisions "undue experimentation by a person having ordinary skill in the art to determine which specific compounds possess the desired utility." This is simply incorrect, especially given the current state of the art in the field of high throughput screening methodologies. Antibacterial screens and RNA binding screens are simple technologies widely available which can support the screening of thousands of compounds on a daily basis. Used in conjunction with modern combinatorial chemistry and rational drug design approaches, researchers no longer need concern themselves with the time involved in running high volumes of compounds through screening experiments. Identification of compounds possessing the desired utility will not require undue experimentation by a person having ordinary skill in the art. Thus, the "breadth of the claims" and the concern of vast numbers of compounds having to be tested will not require undue experimentation due to the advanced state of the art in the field of high-throughput screening.

(B) In this paragraph, Examiner finds reason to doubt the effectiveness of the claimed compounds in the prophylaxis of viral infections, cancer and genetic disorders. The premises of this doubt are "[d]ue to the differing underlying causes" of such disorders, as well as the "unpredictability of treating" such diseases. As stated above, while these diseases may have differing causes, this does not preclude the claimed compounds from having important prophylactic effects against their targets. It is well known by one with ordinary skill in the art that RNA carries the information to code for

all proteins in all cellular processes. Therefore, it is reasonable to expect therapeutically relevant RNAs can be identified for viruses, cancers and genetic disorders. Indeed, many such RNAs have been identified as the transcription products of genes involved in the replication of viruses, as the transcription products of genes involved in the initiation or propagation of cancer cells, and as the transcription products of genes in which mutations give rise to the altered phenotype characteristic of genetic disorders. An example of the latter is cystic fibrosis, referred to specifically below. Since the 2-DOS ring structure, which is found in all the claimed compounds, interacts specifically with RNA, it is reasonable to believe the claimed compounds will possess utility as effective agents in the treatment or prophylaxis of viral infections, cancer and genetic disorders.

(C) Examiner refers to gentamicin, streptomycin and kanamycin being aminoglycosides known for antibacterial activity but not for "prophylaxis and treatment of viral infections, cancers and genetic disorders." Applicant agrees with Examiner to the extent that gentamicin, streptomycin and kanamycin have antibacterial activity. However, these aminoglycosides mentioned by the Examiner, as well as many other members of the streptamine and 2-deoxystreptamine class of aminoglycosides, are known to interact with therapeutically relevant RNAs related to viral infection, cancer and genetic disorders. In fact, it is this knowledge that permits Applicant to extend the scope of the claims to include viral infections, cancer and genetic disorders. Applicant respectfully submits the following examples as evidence of the state of the art in the field that aminoglycosides may be expected to function as vital compounds for the prophylaxis and treatment of viral infections, cancer and genetic disorders: Ribonucleoprotein (RNP)-RNA or RNA-RNA interactions (Hermann, T., *Angew Chem, Int. Ed.*, **2000**, 39, 1890-1905), HIV-1 Rev-RRE (Park W. K. C., Auer M., Jaksche H., Wong C.-H., *J. Am. Chem. Soc.* **1996**, *118*, 10150-5; Zapp M. L., Stern S., Green M. R., *Cell* **1993**, *74*, 969-78; Wang Y., Hamasaki K., Rando R. R., *Biochemistry* **1997**, *36*, 768-79; Kirk S. R., Luedtke N. W., Tor Y., *J. Am. Chem. Soc.* **2000**, *122*, 980-1), HIV-1 *trans*-activating region (TAR), (Wang S., Huber P. W., Cui M., Czarnik A. W., Mei H.-Y. *Biochemistry* **1998**, *37*, 5549-57), hepatitis delta virus, (Chia J. S., Wu H. L., Wang H. W., Chen D. S.,

Chen P. J. *J Biomed Sci.* **1997**, *4*, 208-16) PAX3-FKHR and Bcr-Abl oncogenes (cancer genes), (Sucheck S. J., Greenberg W. A., Tolbert T. J., Wong C.-H. *Angew Chem, Int. Ed.*, **2000**, *39*,1080-3). Aminoglyosides have also been shown to regulate gene expression of the mutant cystic fibrosis transmembrane conductance regulator (CFTR) mRNA by promoting read-through of a mutant stop codon in CFTR (Howard M., Frizzel R. A., Bedwell D. M. *Nature Medicine* **1996**, *2*, 467-9). The above-mentioned examples should indicate the state of the art in the field involves an expectation that the claimed compounds will be successful in providing prophylaxis and treatment of viral infections, cancer and genetic disorders, in addition to the antimicrobial effects previously referenced.

(D) Examiner claims one of ordinary level of skill in the art would expect "only a limited number of aminoglycosides" would actually possess the alleged antibacterial activity. Applicant respectfully submits that the Examiner's claim is unfounded, particularly in light of the 2-DOS ring structure. Aminoglycosides containing this 2-DOS ring structure are expected to have antibacterial activity. Because Applicant's claims are directed to compounds containing the 2-DOS ring structure, it is reasonable to one of ordinary skill in the art to expect the claimed compounds to possess antibacterial activity.

(E) Paragraph E seems to be an amalgam of the previously mentioned issues raised by the Examiner. As mentioned above, compounds containing the 2-DOS ring structure can be predicted to have antibacterial activity and the level of one having ordinary skill in the art is such that screening for antibacterial activity is rapid and highly automated, thereby precluding Examiner's undue experimentation argument. Further, based on the level of ordinary skill in the art, it is reasonable to expect one possessing such ordinary skill to expect the claimed compounds to encompass similar utilities, even though they vary somewhat in terms of chemical structure. In other words, one possessing ordinary skill in the art would presumably recognize the 2-DOS ring structure as the essential pharmacophore giving the invention its utility.

The Examiner also continues to draw the inference that because the claimed compounds contain different structural formulas, it is unlikely such diversity will yield similar utility. As stated above, this inference is improper in that, while the claimed structures have multiple amino groups, enabling the compounds to form complexes with negatively charged RNA, the diversity of the claimed structures in no way hinders the ability of the claimed invention to possess the similar utility across all claimed compounds. Specifically, the claimed compounds have the ability to disrupt therapeutically relevant RNAs, thereby effectuating prophylaxis and treatment of viral infections, cancers (e.g., PAX3-FKHR or Bcr-Abl oncogenes) and genetic disorders (e.g., altering gene expression so as to affect conditions associated with mutant stop codons).

(F) Examiner contends Applicant has failed to provide "direction...as to specific viral infections, cancers and genetic disorders which can be treated with the claimed compounds." Applicant respectfully directs Examiner to page 46, lines 1-9 of the specification, where Applicant provides explicit directions of how the claimed compounds, "based on their ability to interact with RNA are useful for treating viral infection, genetic disorders like muscular dystrophy, cystic fibrosis and cancer." Applicant further cites the Sucheck reference to provide additional information. Additionally, page 1, lines 20-30 of the specification disclose several other bacterial and viral infections that will be targets for the claimed compounds.

(G) Examiner also finds the number of working examples of compounds tested for antibacterial activity is "small." Applicant is unsure as to Examiner's definition of "small" or to what extent compound testing data to surpass the designation of "small". Applicant does, however, respectfully submit the number of working examples is adequately sized so that one of ordinary skill in the art would expect the claimed compounds to be active. This is due to the presence of the 2-DOS ring structure common to active aminoglycosides. Moreover, it is not necessary for Applicant to inundate the specification with working examples. It is only necessary to provide some

data to support the utility of the invention, as well as to provide several preferred embodiments of the invention. *In re Strahilevitz*, 212 U.S.P.Q. 561 (C.C.P.A. 1982). Applicant respectfully submits both necessities have been met.

(H) Examiner again contends undue experimentation in order for one of ordinary skill in the art to make and use the invention. Applicant submits the claimed invention describes compounds containing the 2-DOS ring structure. The specification discloses methods of preparing such claimed compounds and its value in the field will be immense. Further, the actual screening of the compounds described is trivial when one considers the current state of the art in high-throughput screening.

Additionally, Applicant would like to point out that the recitation of the term "prophylaxis" in no way implies that the compounds are used as vaccines with respect to their antimicrobial activity. It is very common in the medical arts to use conventional antibiotics prophylactically in situations in which there is judged to be a significant risk of infection, even though there is no infection present when the antibiotics are first administered. A common instance is dental surgery, where broad-spectrum antibiotics such as tetracycline are administered prophylactically to prevent the risk of infection. Therefore, the use of the term "prophylaxis" does not imply vaccine activity and merely is another reference to the known antibacterial activity of this class of compounds.

IV. THE REJECTION UNDER 35 U.S.C. 112, SECOND PARAGRAPH

Examiner maintains some degree of confusion as to whether claim 1 is a compound or composition claim. Applicant submits claim 1 is a compound claim and makes this more explicit by way of amendment to clarify that claim 1 is a compound claim. Accordingly, the Examiner is respectfully requested to withdraw this rejection as applied to claim 1 as amended.

Examiner contends, as part of the indefiniteness rejection, the scope of the invention is unclear due to the terminology used to describe the claimed matter. Examiner identifies the specific terms at issue, including "modified amino", "modified hydroxyl" and "monoe". Applicant respectfully submits these terms are fully and appropriately explained in the Definitions section of the specification, at page 38, lines 3-8. From the Definitions section, the term "modified amino" includes the terms "protected amino", "amine protecting group", "alkylacylamino", "acylamino" and "carboxamido". The term "modified hydroxyl" includes the terms "protected hydroxyl", "hydroxyl protecting group", "protected hydroxymethyl", "alkoxy", "aryloxy", "acyl", "carboxy esters" and "acyloxy". As the Examiner queries how such modifications occur, Applicant respectfully directs Examiner first to the Aminoglycosides section of the specification, which begins at page 46, where an exhaustive list of example embodiments may be found exhibiting the various modifications to the amino and hydroxyl groups. Applicant then directs Examiner to the Examples section of the specification, beginning at page 81, where Applicant shows how exactly the modifications are carried out as part of the syntheses. For example, Scheme 5 (page 69) shows how the hydroxyl and amine protecting groups (benzo and azido, respectfully) were modified to afford pseudodisaccharide synthesis. This is but one of many examples showing how the modifications were conducted. The specification, therefore, does indeed disclose how such modifications occur, thereby allowing determination of the scope of the invention. The term "monoe", identified by Examiner, is indeed a typographical error. Another term, "mone", appearing on page 13, line 2, is also another typographical error. Both terms were meant to be the word "mono", as used in "monosaccharides". Both typographical errors are corrected by way of amendment, as they are merely word processing errors having no bearing on the claim scope. Examiner also identifies claim 8 as "improper in that it contains a period in the middle of the claim after the term 'carrier'". Applicant agrees with Examiner and has removed the misplaced period by way of amendment because it is merely a word processing error having no bearing on the claim scope.

Examiner further identifies claim 6 as indefinite relative "to whom the compound of formula I is administered". Applicant is a bit confused by this rejection, as claim 6 clearly reads, "A method for treating, preventing, or ameliorating a bacterial infection, a viral infection, a cancer, or a genetic disorder in mammals[,] avian, fish and reptile species as well as in cell culture, which comprises administering a therapeutically effective amount of a compound of formula I or a pharmaceutically acceptable salt, prodrug or solvate thereof..." Taken from the claim language itself, it seems clear the claimed compound may be administered to mammals, birds, fish and reptiles. It may also be administered to cells in culture. Thus, claim 6 is indeed definite in terms of "to whom" the compound of formula I is to be administered. This is further clarified by amendment. The Examiner is therefore respectfully requested to withdraw this rejection.

Applicant also notes Examiner's identification of the duplicative nature of claims 1 and 7. Applicant confesses some confusion regarding this rejection, as claims 1 and 7 have substantial and material differences. Specifically, claim 1 is directed to the compounds alone, while claim 7 includes the compounds plus a carrier.

Examiner insists the phrase "including" renders the associated claims indefinite. Applicant respectfully submits the clarity of the metes and bounds of the associated claims should be viewed in light of the content of the particular application disclosure, prior art teachings and the claim interpretation that would be given by one of ordinary skill in the art. For example, in the specification, at page 46, lines 11-21, there are several embodiments disclosed involving the introduction of novel carbohydrates to the invention. This example showing of the breadth in the specification indicates the breadth of the claims. Thus, because breadth is not indefiniteness, under MPEP § 2173.04, Applicant submits the phrase "including" is proper under the scope of the invention. Nonetheless, to advance prosecution beyond this minor point, Applicant has amended the claims to be more consistent in their claim language. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

With respect to the rejection of claim 2 under the second paragraph of 35 U.S.C. § 112 for incompleteness, Applicant has canceled claim 2 and replaced it with newly presented claim 9, which does recite specific method steps for synthesis of this broad class of compounds. Accordingly, this basis for rejection is now moot.

V. THE REJECTION UNDER 35 U.S.C. § 102(a)/103(a) OVER GHOSHAL ET AL. '456

Examiner contends Applicant's invention is anticipated by and/or obvious in light of Ghoshal et al. '456. Applicant respectfully traverses the rejection for the following reasons:

Ghoshal et al. '456 focuses solely on the derivatives of "naturally occurring aminoglycosides", specifically kanamycin and amikacin. Further, Ghoshal et al. '456 teaches a method of generating a fluorescence based assay for detecting aminoglycoside concentrations in serum. This is accomplished through kanamycin being derivatized at its 1′ position, and amikacin at its 3′ position, with rhodamine or fluorescein or a protein for developing said assay system. No antibiotic activity was ever suggested or claimed for the derivatized aminoglycosides. In fact, Ghoshal et al. '456 teaches away from using aminoglycosides as therapeutic agents because "these antibiotics have a narrow therapeutic index and are potentially nephrotoxic and ototoxic". Thus, Ghoshal et al. '456 would not have even considered making aminoglycosides into a type of prophylaxis or treatment agent, particularly because of the toxic character of the naturally occurring aminoglycosides. The radical nature of the derivatization process suggests the compounds claimed in Ghoshal et al. '456 are unlikely to have microbiological activity, nor were they even created with such a thought in mind. Applicant's claimed compounds, on the other hand, provides novel methods for preparing active aminoglycosides, which differ in sugars around the 2-DOS ring structure, as well

as variation in linkage of additional side chains. Ghoshal et al. '456 is limited to derivatizing naturally occurring aminoglycosides, which are considerably different in their structure and activities when compared to Applicant's claimed compounds. It would not have been obvious to one of ordinary skill in the art to take an aminoglycoside modified to the extent disclosed in Ghoshal et al. '456 for use in fluorescence based assays and attempt to create a therapeutic agent, as described in the instant invention.

When a rejection is made under 35 U.S.C. § 102 or, alternatively under 35 U.S.C. § 103, the prior art must actually disclose a product that reasonably appears to be identical with or only slightly different than a product recited in the prior art. See *In re Brown*, 173 U.S.P.Q. 685 (C.C.P.A. 1972) (product-by-process claim). The considerable difference in structure and activities between the claimed compounds and those disclosed in the '456 patent precludes a rejection alternatively under § 102 or under § 103.

Therefore, neither a § 102(a) nor § 103(a) rejection is proper in light of the distinctiveness of the instant invention, as well as the explicit foreclosure in Ghoshal et al. '456 itself of the idea of creating therapeutic treatments using aminoglycosides. The Examiner is therefore respectfully requested to withdraw this rejection.

VI. THE REJECTION UNDER 35 U.S.C. § 102(a)/103(a) OVER KONDO ET AL. '795

Examiner asserts Kondo et al. '795 is the basis for a rejection under § 102(b) and/or § 103(a). Applicant respectfully traverses the § 102(b)/103(a) rejection for the following reasons:

Applicant respectfully submits that application of the present invention to the compounds of Kondo et al. '795 produces a structure that is significantly distinct from those disclosed in Kondo et al. '795. However, notwithstanding this point,

Applicant further submits Kondo et al. '795 covers four aminoglycosides and methods of preparing the same. Similar to Ghoshal et al. '456, the claimed compounds of Kondo et al. '795 were prepared from naturally occurring aminoglycosides and the methods described are specific to a limited number of naturally occurring aminoglycosides and their derivatives. Namely, the '795 patent is limited to the transformation of the 2′ hydroxyl of naturally occurring 4,6-linked aminoglycosides into 2′ amino as well as the deoxygenation of the 5′ position of the same compounds. Not only are Applicant's methods fundamentally different, but they would not have been obvious to one of ordinary skill in the field at the time of Kondo et al. '795. Rather than being limited to the derivatization of a few naturally occurring aminoglycosides, which requires complex manipulation of protecting groups, as well as numerous steps to execute synthesis, Applicant submits the methods of the instant invention allows for a host of new aminoglycosides with potent antimicrobial activity by introducing new carbohydrate units onto the 2-DOS ring system. For example, arebekacin and dibekacin contain a 3-aminoglucose linked to the 6′ position of the 2-DOS ring. The limit of Kondo et al. '795 is that it only allows for the conversion of the 2′ hydroxyl into 2′ amino. The methods of the present invention allow for the complete replacement of ring I or III of 4,6-linked aminoglycoside compounds. Thus, 3-aminoglucose can be replaced with 2-methylamino-3-methylamino-galactosyl in the present invention, which would have been unlikely to have been achieved using the '795 invention, which is limited to relatively simple manipulation of a natural aminoglycoside. Furthermore, Applicant's methods allow one to prepare structures and aminoglycosides containing novel substituents at almost any position of the carbohydrate rings. The present invention yields an enormous number of novel aminoglycosides that were neither considered, nor possible to create, using the methods disclosed in Kondo et al. '795.

Accordingly, there is no basis for a rejection of these claims under over Kondo et al. '795 under either 35 U.S.C. § 102 or § 103. The Examiner is therefore respectfully requested to withdraw these rejections.

VII. CONCLUSION

In conclusion, the claims remaining for consideration are fully enabled by the specification, are complete, and particularly point out and distinctly claim that which Applicant regards as his invention. These claims are neither anticipated by nor obvious over the prior art, whether the prior art is considered individually or in combination. Accordingly, prompt allowance of these claims is respectfully requested.

Respectfully Submitted,

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Jeff Landes, Esq., Reg. No. 55,355
Attorney for Applicant

CATALYST LAW GROUP, APC
4220 La Jolla Village Drive, Suite 220
San Diego, California 92122
(858) 450-0099
(858) 450-9834 (Fax)